

WHAT IS CLAIMED IS:

1. A microparticle composition for controlling an immune response by downregulating a pathologic arm of the immune system, or upregulating the suppressor arm of the immune system, or simultaneously downregulating the pathogenic arm and upregulating the suppressor arm of the immune system comprising:

a surfactant or mixture of surfactants comprising approximately 1 – 80% of the weight of the total microparticle composition;

at least one excipient selected from the group consisting of carbohydrates, polyols, salts, proteins and synthetic polymers; and,

at least one antigen.

2. The microparticle composition of claim 1 wherein the antigen is selected from the group consisting of foreign antigens and self-antigens.

3. The microparticle composition of claim 1 wherein the antigen is a protein antigen.

4. The microparticle of claim 3 wherein the protein antigen is an immunoglobulin or an immunoglobulin-like molecule.

5. The microparticle composition of claim 1 wherein the microparticle composition suppresses an ongoing deleterious immune response.

6. The microparticle composition of claim 1 wherein the microparticle composition prevents a deleterious immune response.

7. The microparticle composition of claim 1 wherein the microparticle composition prevents, suppresses or limits an immune response against a delivered bioactive payload.

8. The microparticle composition of claim 7 wherein the payload is a peptide hormone.

9. The microparticle composition of claim 1 wherein the microparticle composition enhances induction of a Th2 cellular response.

10. The microparticle composition of claim 9 wherein the microparticle composition induces an enhanced expression of IL-4.

11. The microparticle composition of claim 1 wherein the microparticle composition enhances induction of a humoral response.

12. The microparticle composition of claim 11 wherein the humoral response is directed against a foreign epitope or tumor associated antigens.

13. The microparticle of claim 12 wherein the foreign epitope is selected from the group consisting of microbial epitopes and parasitic epitopes.

14. The microparticle composition of claim 1 wherein the microparticle is compatible with deep lung delivery.

15. The microparticle of claim 1 wherein the surfactant is selected from the group consisting of phosphatides, non-ionic surfactants, cationic surfactants, proteins, amino acids and oligoaminoacids.

16. The microparticle of claim 8 wherein the phosphatide surfactant is chosen from the group consisting of homo and heterochain PC's, PS's, PE's, PG's, PI's, sphingomyelins, gangliosides, TAP's and DAP's, having one or two hydrocarbon chain length ranging from 5 to 22 carbon atoms.

17. The microparticle of claim 8 wherein the phosphatides may be hydrogenated, unsaturated or partially hydrogenated.

18. The microparticle of claim 17 wherein the phosphatides are phosphatides derived from soy or egg.

19. The microparticle composition of claim 15 wherein the phosphatide is selected from the group consisting of DiC18PC, DiC16PC, DiC14PC, DiC8PC, DiC6PC, DiC16PS, DiC14PS, DiC8PS and DiC6PS.

20. The microparticle composition of claim 15 wherein the non-ionic surfactant is selected from the group consisting of poloxamers, tweens, tritons, PEGs, and sugar esters.

21. The microparticle composition of claim 15 wherein the non-ionic surfactant is selected from the group consisting of poloxamer 188, poloxamer 407, tween 80, PEG 1540, cetyl alcohol and tyloxapol.

22. The microparticle composition of claim 15 wherein the non-ionic surfactant is selected from the group consisting of benzalkonium chloride, cholate, deoxycholates, CHAPs, taurocholate, deoxytaurocholate, phosphate fatty acid salts like dicetyl phosphate.

23. The microparticle composition of claim 1 wherein the at least one surfactant is selected from the group consisting of albumin, leucine, oligopeptides, oligoleucine, oligoalanine and saponins.

24. The microparticle composition of claim 1 wherein the carbohydrate excipient is selected from the group consisting of include hetastarch, starches, lactose, mannitol, mannose,

inulin, mannan, sorbitol, galactitol, sucrose, trehalose, raffinose, maltose, glucose, cellulose and derivatives, pectins, dextrans, dextrans, chitosan, chitin, mucopolysaccharides, chondroitin sulfate and saponins.

25. The microparticle composition of claim 1 wherein the protein excipient is selected from the group consisting of human, egg or bovine albumin, chollagen, oligopeptides, oligoleucine, oligoalanine, gelatin, and glycoproteins.

26. The microparticle composition of claim 1 wherein the synthetic polymer excipient is selected from the group consisting of PLGA's, polylactides, polyglycolides, PVA's, PVP's, polyacrylics, carbomers, polyanhydrides, polyphosphoethers, polyurethanes, polyesters and polyphosphazenes.

27. The microparticle composition of claim 1 wherein the microparticle composition is delivered to the respiratory tract.

28. The microparticle composition of claim 1 wherein the antigen is insulin.

29. The microparticle composition of claim 1 wherein the formulated antigen, antigen fragment or antigen integrated into a recombinant molecule is disease associated and selected from the group consisting of insulin, GAD, HSP, collagen, MBP, PLP, and MOG.

30. The microparticle composition of claim 1 wherein the formulated antigen, antigen fragment or antigen integrated into a recombinant molecule is microbial associated selected from the group of microbes consisting of influenza, HIV, rotavirus, respiratory syncitial virus, hepatitis B, A, C, D, poliovirus, measles, mycobacteria tuberculosis, leishmania, listeria, pseudomonas, streptococcus and meningococcus.

31. The microparticle composition of claim 1 further comprising tyloxapol.

32. A microparticle composition for the treatment of an autoimmune disorder comprising:

at least one surfactant wherein the at least one surfactant comprises approximately

1 - 80% of the total weight of the microparticle composition;

a carbohydrate that binds to the lectin receptors on antigen presenting cells; and
an antigen.

33. The microparticle composition of claim 32 wherein the autoimmune disorder is type 1 diabetes.

34. The microparticle composition of claim 32 wherein the main surfactant is a phosphatide.

35. The microparticle of claim 32 wherein the main surfactant is a phosphatidylcholine.

36. The microparticle composition of claim 35 wherein the main surfactant is a partially or hydrogenated phosphatidylcholine from egg or soy.

37. The microparticle composition of claim 32 wherein the lectin receptor is a mannose receptor.

38. The microparticle composition of claim 37 wherein the carbohydrate is mannan.

39. The microparticle composition of claim 32 wherein the antigen is insulin.

40. The microparticle composition of claim 39 wherein the antigen is insulin B chain.

41. The microparticle composition of claim 32 wherein the carbohydrate includes microbial or synthetic carbohydrates or derivatives.

42. A method of treating a patient suffering from Type 1 diabetes by administration of a therapeutically effect amount of microparticles as described in claim 32.

43. A method if treating a patient suffering from Type 1 diabetes by administration of a therapeutically effective amount of microparticles as described in claim 38.

44. The method of claim 42 wherein the patient is treated during the early initiation phase of insulinitis.

45. The method of claim 42 wherein the patient is treated during later pathogenic stages of Type 1 diabetes associated with active islet cell destruction.

46. A method of enhancing the Th2 response of an individual suffering from an autoimmune disorder comprising administration of a therapeutically effective amount of the microparticle composition of claim 32.

47. A method of enhancing the Th2 response of an individual suffering from an autoimmune disorder comprising administration of a therapeutically effective amount of the microparticle composition of claim 40.

48. A method of enhancing the IL-4 production of an individual suffering from an autoimmune disorder comprising administration of a therapeutically effective amount of the microparticle composition of claim 32.

49. A method of tolerizing pathogenic T-cells in an individual suffering from autoimmune diabetes comprising administration of a therapeutically effective amount of the microparticle composition of claim 37.

50. A method of preventing the onset of Type 1 diabetes by administration of a therapeutically effective amount of the microparticle composition of claim 32.

51. A microparticle composition for the treatment of an autoimmune disorder comprising:

a surfactant or surfactant mixture comprising approximately 1 - 80% of the total weight of the microparticle composition; and

a carbohydrate that binds to the lectin receptors on antigen presenting cells comprising approximately 1 - 60% of the total weight of the microparticle composition.

52. The microparticle composition of claim 51 wherein the main surfactant is a phosphatide.

53. The microparticle composition of claim 51 wherein the lectin receptor is a mannose receptor.

54. The microparticle composition of claim 51 wherein the carbohydrate is mannan.

55. The microparticle composition of claim 51 wherein the main surfactant is a partially or hydrogenated phosphatidylcholine from egg or soy.

56. A method of preventing the development of type 1 diabetes comprising administering a therapeutically effective amount of the microparticle compositions of claim 51.

57. A method of preventing the development of type 1 diabetes comprising administering a therapeutically effective amount of the microparticle composition of claim 53.

58. A method of preventing the development of type 1 diabetes comprising administering a therapeutically effective amount of the microparticle composition of claim 54.

59. A method of enhancing the Th2 response of an individual suffering from an autoimmune disorder comprising administration of a therapeutically effective amount of the microparticle composition of claim 51.

60. A method of tolerizing pathogenic T-cells in an individual suffering from autoimmune diabetes comprising administration of a therapeutically effective amount of the microparticle composition of claim 51.

61. A microparticle composition for delivering a bioactive substance where it is desired to limit the immune response to the bioactive substance comprising:

a water soluble surfactant selected from the group consisting of: phosphatides, non-ionic surfactants, anionic surfactants, cationic surfactants, proteins, amino acids and oligoaminoacids;

a water soluble excipient comprising a weight ratio of 1–90% of the total weight of the composition wherein the water soluble excipients is selected from the group consisting of lactose, mannitol, mannose, sorbitol, galactitol, sucrose, trehalose, raffinose, maltose, glucose, saponins, osmotic agents such as sodium chloride, potassium chloride, calcium chloride, magnesium chloride, zinc chloride, buffers such as PBS, acetate, citrate, TRIS and amino acids such as glycine and alanine; and,

a bioactive substance.

62. The microparticle composition of claim 61 wherein the bioactive substance is insulin.

63. The microparticle composition of claim 61 wherein the microparticle composition is administered to the respiratory tract.

64. The microparticle composition of claim 61 wherein the microparticle composition results in a less retentive microparticle which has a high dissolution rate in water.

65. The microparticle composition of claim 61 wherein the microparticle composition results in a high dissolution rate and a low clearance by phagocytes in the respiratory tract.

66. The microparticle composition of claim 61 wherein the microparticle composition limits the Th2 immune response.

67. The microparticle of claim 61 further comprising a metal ion.

68. The microparticle composition of claim 61 further comprising tyloxapol.

69. The microparticle of claim 61 wherein the surfactant or mixture of surfactants is present in an amount of approximately 1 - 80% of the total weight of the microparticle composition.

70. A microparticle composition for delivering a bioactive substance where it is desired to enhance the immune response to the bioactive substance comprising:

a surfactant or mixture of surfactants selected from the group consisting of phosphatides, non-ionic surfactants, anionic surfactants, cationic surfactants, proteins, amino acids and oligaminoacids;

an excipient selected from the group consisting of starches, lactose, mannitol, mannose, inulin, mannan, sorbitol, galactitol, sucrose, trehalose, raffinose, maltose, glucose, cellulose and derivatives, pectins, dextrans, dextrans, chitosan, chitin, mucopolysaccharides, chondroitin sulfate, saponins osmotic agents such as sodium chloride, potassium chloride, calcium chloride, magnesium chloride, zinc chloride, buffers such as PBS, acetate, citrate, TRIS, amino acids such as glycine and alanine, human, egg or bovine albumin, chollagen, oligopeptides, oligoleucine, oligoalanine, gelatin, glycoproteins, PLGA's, polylactides, polyglycolides, PVA's, PVP's, polyacrylics, carbomers, polyanhydrides, polyphosphoethers, polyurethanes, polyesters and polyphosphazenes;

and a bioactive substance for inducing an immune response.

71. The microparticle composition of claim 70 wherein the microparticle composition is administered to the respiratory tract.

72. The microparticle composition of claim 70 wherein the bioactive substance is insulin.

73. The microparticle composition of claim 70 wherein the microparticle composition results in a retentive microparticle which slows the release of the bioactive substance.

74. The microparticle composition of claim 70 wherein the microparticle composition results in aggregation and slows clearance by phagocytes in the respiratory tract.

75. The microparticle composition of claim 70 wherein the microparticle composition increases the Th2 immune response.

76. The microparticle of claim 70 further comprising a metal ion.

77. The microparticle composition of claim 70 wherein a non-ionic surfactant is added to increase the release rate of the bioactive substance.

78. The microparticle composition of claim 77 wherein the non-ionic surfactant is tyloxapol.

79. The microparticle composition of claim 70 wherein the bioactive substance is selected from the group consisting of nucleic acids, nucleotides, peptides and proteins.

80. The microparticle composition of claim 1 wherein the microparticle composition can be administered to the respiratory tract by liquid dose instillation, nebulization, aerosolization, dry powder inhalation and metered dose instillation.